K132180

JUN 25 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of the SMDA and 21 CFR 807.92.

1. Submitter's information

Name:	Ideal Life Inc.
Address:	2200 Yonge Street, Suite 1300 Toronto ON M4S 2C6
Phone number:	(416) 489-1494
Fax number:	(416) 489-3009
Contact:	Jason Goldberg
Date of Summary:	May 16, 2014

2. Device Information

Trade name:	IDEAL LIFE Gluco-Manager™ Blood Glucose Monitoring System, Model GMM0002
Common name:	Blood Glucose Monitoring System
Classification name:	Blood Glucose Monitoring System

3. Classification

Product code:	NBW, Blood Glucose Monitoring System CGA, Glucose Test System JQP, Calculator/data processing module for clinical use JJX, Quality Control Material (assayed and unassayed)
Regulation number:	862.1345
Class:	2
Panel:	Clinical Chemistry

4. Predicate Device Information

Manufacturer:	Andon Medical Co., Ltd.
Device:	AG-608N Single Blood Glucose Monitoring System
510(k) Number:	K110017

5. Device Description

The IDEAL LIFE Gluco-Manager™ Blood Glucose Monitoring System, Model GMM0002 consists of a blood glucose meter, single use test strips and control solution.

The new device IDEAL LIFE Gluco-Manager™, Model GMM0002 is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 5 seconds. The control solution available is used to test the performance of the device. It uses the same technological characteristics for testing with its predicate device.

The IDEAL LIFE Gluco-Manager™ can be used alone to measure your blood glucose. If the user would like to transmit blood glucose information for display on a personal computer, the IDEAL LIFE Gluco-Manager™ can wirelessly communicate with a communication gateway (the optional IDEAL LIFE Pod™) or by using the Gateway Application, a mobile medical application.

6. Intended Use

The IDEAL LIFE GlucoManager™ Blood Glucose Monitoring System, Model GMM0002 is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip or alternative sites (palm, forearm, upper arm, calf, and thigh). The system is intended to be used by a single patient and should not be shared.

The IDEAL LIFE GlucoManager™ Blood Glucose Monitoring System, Model GMM0002 is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should only be done during steady state times when blood glucose is not changing rapidly.

The IDEAL LIFE Blood Glucose Test Strips, Model AGS-1112 are for use with the IDEAL LIFE GlucoManager™ to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips, palm, forearm, upper arm, calf, and thigh.

The IDEAL LIFE Control Solution, Model GCS-0104 is intended for use with IDEAL LIFE GlucoManager™ and IDEAL LIFE Blood Glucose Test Strips, Model AGS-1112. The control solution can be used to check that the glucose meter and test strips are working properly and that the measurement is accurate.

The IDEAL LIFE GlucoManager™ can wirelessly communicate with a communication gateway such as the IDEAL LIFE Pod™ or the IDEAL LIFE Gateway Application™. The IDEAL LIFE Gateway Application receives data wirelessly from IDEAL LIFE devices to transmit over the Internet from the user's mobile device. The Gateway Application is intended to aid people at home and health care professionals to review and evaluate historical blood glucose results, to support effective health care management.

The IDEAL LIFE Gateway Application™ makes no interpretation, evaluation, medical judgment or recommendations for treatment. This device is not intended as a substitute for medical care.

7. Comparison of Technological Characteristics with Predicate Device

CHARACTERISTIC	NEW DEVICE: IDEAL LIFE Gluco-Manager™ Model GMM0002	PREDICATE DEVICE: AG-608N Single GBMS (K110017)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)
Sample Source	Capillary whole blood from AST (Alternative site testing) and finger	Capillary whole blood from AST (Alternative site testing) and finger
Sample Application	Blood sample is placed directly to the test strip after finger or AST is lanced	Blood sample is placed directly to the test strip after finger or AST is lanced
Hematocrit Range	20-60%	20-60%
Operating Temperature Range	10°C to 40°C (50°-104°F)	10°C to 40°C (50°-104°F)
Dimensions	77.3mm × 60.2mm ×25mm	87mmx 53mmx 9.9mm
Display	LCD	LCD
Result Presentation	mg/dL or mmol/L	mg/dL or mmol/L
Memory Capabilities	575 times with time and date display	500 times with time and date display
Test Start	Automatic	Automatic
Test Time	5 seconds	5 seconds
Power Source	DC 3V (2*AAA batteries)	DC 3V (CR2032)
Battery Life	Over 200 determinants	Approx. 500 normal tests
Measurement Range	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)	20mg/dL-600mg/dL (1.1mmol/L~33.3mmol/L)
Qualified Test Strip	AGS-1112 Test Strip	AGS-1000N Test Strip
Sample Volume	Minimum 0.7 micro liter	Minimum 0.7 micro liter
Other functionality	Bluetooth function to upload data to IDEAL LIFE website	USB function

8. Performance Summary

IDEAL LIFE Gluco-Manager™ GMM0002 Blood Glucose Monitoring System conforms to the following standards:

- ISO 15197: In vitro diagnostic test systems- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- IEC 61010-1: 2001, Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1:General requirements.
- IEC 61010-2-101: 2002,Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
- EN 61326-1:2006, Electrical equipment for measurement, control and laboratory use – EMC requirements part 1: General requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

IDEAL LIFE INC.
C/O DIANE HORWITZ
MANDELL HORWITZ CONSULTANTS LLC
2995 STEVEN MARTIN DRIVE
FAIRFAX VA 22031

June 25, 2014

Re: K132180
Trade/Device Name: IDEAL LIFE GlucoManager™ Blood Glucose Monitoring System, Model GMM0002
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JQP, JJX
Dated: June 16, 2014
Received: June 16, 2014

Dear Ms. Diane Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132180

Device Name
IDEAL LIFE GlucoManager™ Blood Glucose Monitoring System, Model GMM0002

Indications for Use *(Describe)*
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Type of Use *(Select one or both, as applicable)*.

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S